## Who can attend?

**Academia**: Students, Faculty members & Research scholars from Pharmacy/ Life sciences.

**Industry**: Scientists, Regulatory and Quality Assurance professionals, Pharmaceutical & Biosciences industry professionals.

No of credits:01

<b>Registration Details</b>	
Registration fee	MAHE Students/ Staff:
(Inclusive of GST)	INR 1250/-
	<b>Others:</b> INR 1500/-
Registration	5 September 2018
deadline	
Number of participants to workshop is limited	

Registration fee should be paid ONLINE

Beneficiary name: Manipal University

**Conference/Workshop** 

ONLY

Name of the bank: State Bank of India

to 60, on first-cum-first-serve basis.

Branch name: Manipal

Bank account number: 33508958510

IFSC code: SBIN0004426

Registration fee includes participation, workshop kit and lunch.

**Note**: Please email registration fee transaction details to **cgmp.mcops@gmail.com** 

We extend a warm welcome to delegates for an eventful interaction at Manipal.

# How to register?

- Visit the website: https://conference.manipal.edu/cgmp2018
- Make the payment online
- Fill the form & submit

#### Venue

Manipal College of Pharmaceutical Sciences, Manipal Academy of Higher Education (MAHE), Manipal – 576104, Karnataka, India



## Accommodation

The following are the suggested options for accommodation close to the venue. Participants are requested to directly contact the hotels for booking.

**Manipal:** Green Park, Hill View, Madhuvan Serai and Ashlesh.

**Udupi:** Kediyoor Hotel, Udupi Residency, Sriram Residency and Swadesh Heritage.

**Campus accommodation:** Accommodation will be arranged within university campus at affordable charges upon request.

## For more details, contact:

Dr. Girish Pai K Dr. Girish Thunga

Email: cgmp.mcops@gmail.com





# National workshop on cGMP, Compliance and Data Integrity

21-22 September 2018

Organised by **GMP unit** 

Manipal College of Pharmaceutical Sciences Manipal Academy of Higher Education Manipal - 576 104 Karnataka, India.



in association with **Medorganics India Pvt Ltd** (A division of **MEDITEK India**)



### **About MAHE**

MAHE (Manipal Academy of Higher Education) is synonymous with excellence in higher education.

Over 28,000 students from 57 different nations live, learn and play in the sprawling university town. It also has nearly 2500 faculty and almost 10000 other support and service staff, who cater to the various professional institutions in health sciences, engineering, management, communication and humanities.

MAHE is ranked #1 among private universities in India in QS world ranking 2018. MAHE is also accorded as an "Institute of Eminence" in 2018 by Ministry of HRD, Govt. of India.

#### **About MCOPS & GMP unit:**

Manipal College of Pharmaceutical Sciences (MCOPS), a constituent unit of MAHE, Manipal was established in 1963. MCOPS offers DPharm, BPharm, MPharm, PharmD, PharmD Post Baccalaureate and PhD programmes. The college is ISO 9001:2008 and ISO14001:2004 certified. MCOPS has been ranked #7 amongst Pharmacy Institutions of India by NIRF, MHRD, Govt. of India in 2018.

GMP unit is a unique industry institute collaboration which is first of its kind in pharmaceutical space established in June 2018 in association with Medorganics India Pvt Ltd. The main objective is to bridge the gap between industry and academia, identify the training needs as per current regulatory/industry requirements and to tap technical experts from reputed pharmaceutical companies/academia as trainers for such programs that will benefit the delegates.

Importance of this workshop is to cultivate a strong Quality Culture and Data Integrity System right from academic set up which is the need of the hour, especially for Indian pharmaceutical sector.

Data Integrity is nothing but completeness, consistency and accuracy of data. The data should be attributable, legible, contemporaneously recorded, original or a true copy, and accurate. It is an important component of pharmaceutical industry's responsibility to ensure the safety, efficacy, and quality of medicines, and of FDA's ability to protect the public health.

# **Topics**

## Day 1

- 1. cGMP in pharmaceuticals
- 2. Basics of GMP & Quality unit functions and responsibilities (QA and QC)
- 3. Good Documentation Practices (GDP)

# Day 2

- 1. Good Laboratory Practices (GLP)
- 2. Data Integrity and Quality Culture
- 3. Case studies: FDAs recent GMP observations and Data integrity issues.

We acknowledge the support of Hetero Labs Ltd and Medorganics India Pvt Ltd.



#### **Resource Persons**

- 1. Dr. Venkatakrishna K, Medorganics India Pvt Ltd, Mangalore
- 2. Dr. Akhilesh Dubey, NGSM Institute of Pharmaceutical Sciences, NITTE (Deemed to be University), Mangalore
- 3. Dr. Krishnananda Kamath, Srinivas College of Pharmacy, Srinivas University, Mangalore
- 4. Dr. Muddukrishna B S, Manipal College of Pharmaceutical Sciences, MAHE, Manipal
- 5. Dr. Girish Pai K, Manipal College of Pharmaceutical Sciences, MAHE, Manipal

# **Organizing Committee**

#### Advisors

- 1. Dr. N. Udupa
- 2. Dr. C. Mallikarjuna Rao
- 3. Dr. M. Sreenivasa Reddy

# **Coordinators**

- 1. Dr. K. B. Koteshwara
- 2. Dr. Mahadev Rao
- 3. Dr Girish Pai K
- 4. Dr Girish Thunga

#### **Members**

- 1. Dr. Srinivas Mutalik
- 2. Dr. Shaila Lewis
- 3. Dr. Mahalaxmi Ratnanand
- 4. Dr. Usha Y Nayak
- 5. Dr. Anup Naha
- 6. Dr. Vamshi Krishna T
- 7. Dr. Lalit Kumar
- 8. Ms. Jyothsna M
- 9. Mrs. Aswathi R H